February 28, 1992

MEMORANDUM

SUBJECT: Transmittal of EFED Review for Allium sativum

FROM: Amy Rispin, Chief Aug

Science Analysis and Coordination Staff Environmental Fate and Effects Division

TO: Jay Ellenberger, Chief

Generic Chemical Support Branch

Special Review and Reregistration Division

Attached please find the following documents for the completed EFED review of Allium sativum.

1. SACS Reregistration Summary Report

2. Memo from Amy Rispin to Jay Ellenberger

3. Memo from Anne Barton to Dan Barolo

If you have any questions concerning this case, please contact Bernice Slutsky (305-7974).

cc (with SACS Reregistration Summary Report attached)

Anne Barton Amy Rispin Cover Memo File Hank Jacoby Elizabeth Loevey Doug Urban Norm Cook

SACS REREGISTRATION SUMMARY REPORT

FROM: Bernice Slutsky

Date: February 28, 1992

THRU: Amy Rispin any Rispin

TO: Margarita Collantes

Active Ingredient:

Allium sativum (garlic)

EFED will not preform a science review for Allium sativum (garlic) and, therefore, will not require any studies to be submitted for reregistration (see attached memo from Amy Rispin to Jay Ellenberger). The rationale for this is outlined in the attached memo dated 1/13/92 from Anne Barton to Dan Barolo.

Attachments

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

EFED Policy for Reregistration of Putrescent Whole Egg

Solids (Case 4079), Citric Acid (Case 4024) and Capsaicin

(Case 4018).

Amy Rispin, Chief SACS From:

any Kisperi

Anne Barton, Director EFED Thru:

Jay Ellenberger, Chief ARB To:

EFED will not perform a science review for Putrescent Whole Egg Solids, Citric Acid or Capsaicin. Instead, we recommend that a workgroup develop a solution for reregistration of these products and make appropriate decisions about labelling. Therefore, EFED will not require any studies to be submitted for reregistration. The rationale for not requiring studies is based on the same rationale as outlined for garlic in the attached memo dated 1-13-92 from Anne Barton to Dan Barolo. This rationale has been based on the wide availability of these compounds as food.

cc: D. Barolo - H 7508W-Spee Review

- H. Jacoby
- D. Urban



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Policy For Handling Reregistration For Active Ingredients

Which Are Widely Available as Non-Pesticide

FROM: Anne L. Barton, Director On 1 Det 1/13/92

Environmental Fate and Effects Division (H7507C)

TO : Dan Barolo, Director

Special Review and Reregistration Division (H7508W)

In the recent RED review for garlic (attached), EEB has shown that we cannot make a case for 1) low risk, 2) low exposure or 3) low incremental risk or exposure to aquatic organisms. However, I believe that the program would be unwilling to require even the basic toxicity studies normally required for a biochemical.

In thinking about the rationale for waiving these data, I have come to the conclusion that it has to do with the wide availability of the compound as a food. If people wanted to apply garlic in the manner covered by the pesticide label, they would not necessarily have to buy a registered pesticide because garlic is available in many forms at the grocery store.

Please note that this is not the same as a rationale based on ubiquity. I believe EEB is able to show that garlic is <u>not</u> in fact ubiquitous in the aquatic environment, aside from any pesticide use (therefore we are unable to make a low incremental risk case.) The rationale I am proposing is actually not a risk argument at all.

Therefore I would like to propose that we decide <u>as a program</u> to waive all risk-based data requirements (i.e., all EFED and HED requirements) for products which are widely available as food or related items. If you agree, I think we should set up an interdivisional work group to confirm the feasibility of sound policy to work out the policy statement and details.

Attachment

DECISIONE I

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